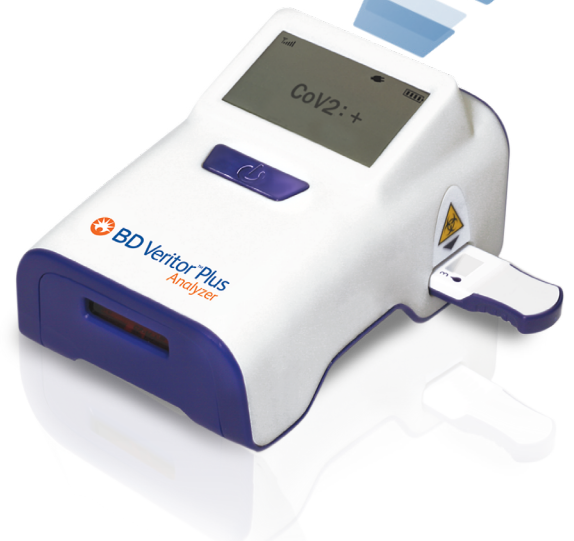


Interpreting COVID-19 test results

It is important to understand how local disease prevalence rate and test performance characteristics interact to influence the proportion of false positive test results compared to all positive results. The infographic below demonstrates how very low, low, medium, and high prevalence rates make a difference. It is important to note that your institution's specific prevalence rates can be used to calculate the potential in your facility.

Understanding that false positive test results are a possibility is important. Please follow your institution and/or province and local guidance for addressing a patient with a positive test result. Guidance may include precautionary isolation procedures and a second mode of testing for confirmation.



Hypothetical false positive rates based on prevalence



Why false positives might occur

Even the most highly-accurate tests can produce false positive results. False positives are expected for all diagnostic tests, involving all detection technologies: PCR, antigen assays, etc. In the case of antigen tests (such as BD Veritor™ Plus System†), test results could be influenced by a number of factors:

- Workflow inconsistencies
- Quality of test sample
- Not following instructions for use

BD Veritor™ Plus System has a 98%–100% specificity, which means the false positive rate is less than 2% of all the tests performed. This means when you use your BD Veritor™ Plus System you might see 0–2 false positives for every 100 tests you conduct. If a customer sees rates of false positives higher than 2% of all the tests performed, this would be outside of the performance we would expect. Any false positive should be reported to BD for further investigation.

Key terms to understand with COVID-19 testing

Understanding the specifics of test performance can be complex. Below is the list of test performance terminology which may help you to better understand.

- **Pretest Probability:** Probability of a patient having an infection before the test result is known; based on the proportion of people in a community with the disease at a given time (prevalence) and the clinical presentation of the patient.
- **Negative Predictive Value:** Probability that a patient who has a negative test result truly does not have the infection.
- **Positive Predictive Value:** Probability that a patient who has a positive test result truly does have the infection.
- **False Positive Result:** A test result indicating the infection is present when it is not.
- **True Negative Result:** A test result correctly indicating that the infection is not present.
- **False Negative Result:** A test result indicating the infection is not present when it is.
- **True Positive Result:** A test result correctly indicating that the infection is present.



† Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

- This test has been authorized for sale in Canada by Health Canada under Interim Order;
- This test is only authorized for the duration of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, unless the authorization is terminated or revoked sooner;
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.